



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. FDA-2015-N-3838]

Medical Devices; General Hospital and Personal Use Devices; Classification of the Ultraviolet Radiation Chamber Disinfection Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is classifying the ultraviolet (UV) radiation chamber disinfection device into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the UV radiation chamber disinfection device classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The classification was applicable on December 20, 2011.

FOR FURTHER INFORMATION CONTACT: Elizabeth Claverie, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2508, Silver Spring, MD, 20993-0002, 301-796-6298.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1) of the FD&C Act. Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to

undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of “low-moderate risk” or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will be the initial classification of the device. In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on October 28, 2010, classifying the Vioguard Self-Sanitizing Keyboard into class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II. On November 2, 2010, Vioguard submitted a request for classification of the Vioguard Self-Sanitizing Keyboard under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act. FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on December 20, 2011, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 880.6600.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for a UV radiation chamber disinfection device will need to comply with the special controls named in this final order. The device is assigned the generic name UV radiation chamber disinfection device, and it is identified as a UV chamber disinfection device intended for the low-level surface disinfection of non-porous equipment surfaces by dose-controlled UV irradiation. This classification does not include self-contained open chamber UV disinfection devices intended for whole room disinfection in a health care environment.

FDA has identified the following risks to health associated specifically with this type of device, as well as the mitigation measures required to mitigate these risks in table 1.

Table 1.--Ultraviolet Radiation Chamber Disinfection Device Risks and Mitigation Measures

Identified Risks	Mitigation Measures
Inadequate Equipment Disinfection	Performance Testing Labeling
UV Radiation Exposure	Performance Testing Labeling
Electrical Shock	Electrical Safety Testing
Electromagnetic Interference	Electromagnetic Compatibility (EMC) Testing Labeling
Ozone Exposure	Ozone Generation Limits Labeling
Processed Equipment Incompatibility	Performance Testing Labeling
Contamination of Device	Cleaning and Disinfection Validation Labeling
Software Malfunction	Hazard Analysis of Software Software Verification and Validation

FDA believes that the special controls in § 880.6600(b)(1) through (4), in addition to the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the UV radiation chamber disinfection device they intend to market.

II. Environmental Impact

We have determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910-0120,

and the collections of information in 21 CFR part 801, regarding labeling have been approved under OMB control number 0910-0485.

IV. Reference

The following reference is on display in the Division of Dockets Management (see ADDRESSES) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at <http://www.regulations.gov>.

1. DEN100013: de novo request per 513(f)(2) from Vioguard, dated November 2, 2010.

List of Subjects in 21 CFR Part 880

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 880 is amended as follows:

PART 880--GENERAL HOSPITAL AND PERSONAL USE DEVICES

1. The authority citation for 21 CFR part 880 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 880.6600 is added to subpart G to read as follows:

§ 880.6600 Ultraviolet (UV) radiation chamber disinfection device.

(a) Identification. An ultraviolet (UV) radiation chamber disinfection device is intended for the low-level surface disinfection of non-porous equipment surfaces by dose-controlled UV irradiation. This classification does not include self-contained open chamber UV radiation disinfection devices intended for whole room disinfection in a health care environment.

(b) Classification. Class II (special controls). The special controls for this device are:

- (1) Performance testing must demonstrate the following:

- (i) The chamber's ability to control the UV radiation dose during operation.

- (ii) The chamber's disinfection performance through microbial challenge testing.
 - (iii) Evidence that the equipment intended to be processed is UV compatible.
 - (iv) Validation of the cleaning and disinfection procedures.
 - (v) The ability of the device to continue to perform to all specification after cleaning and disinfection.
 - (vi) Whether the device generates ozone (if so, 21 CFR 801.415, Maximum acceptable level of ozone, applies).
- (2) Appropriate software verification, validation, and hazard analysis must be performed.
- (3) Appropriate analysis and/or testing must validate electrical safety, mechanical safety, and electromagnetic compatibility of the device in its intended use environment.
- (4) The labeling must include:
- (i) UV hazard warning labels.
 - (ii) Explanation of all displays and/or labeling on user interface.
 - (iii) Explanation of device safety interlocks.
 - (iv) Explanation of all disinfection cycle signals, cautions and warnings.
 - (v) Device operating procedures.
 - (vi) Identification of the expected UV lamp operational life and instructions for procedures on replacement of the UV lamp when needed.
 - (vii) Procedures to follow in case of UV lamp malfunction or failure.
 - (viii) Procedures for disposing of mercury-containing UV lamps, if applicable.

(ix) Identification of specific equipment that is compatible with the UV radiation dose generated by the device and that can safely undergo UV radiation low-level disinfection in the chamber device.

(x) Description of the required preparation of equipment for disinfection in the UV radiation chamber device.

(xi) Identification of the specific microbes used in successful performance testing of the device.

(xii) Validated instructions for cleaning and disinfection of the device.

Dated: November 17, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-29660 Filed: 11/19/2015 8:45 am; Publication Date: 11/20/2015]